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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,464	11/08/2001	Goran Karlsson	2081.0020001/EEF	5096

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EXAMINER

MELLER, MICHAEL V

ART UNIT PAPER NUMBER

1654

DATE MAILED: 12/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/986,464

Applicant(s)

KARLSSON, GORAN

Examiner

Michael V. Meller

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 17, 18, are rejected under 35 U.S.C. 102(b) as being anticipated by Miller-Andersson et al.

The reference teaches that antithrombin III is purified using affinity chromatography using ammonium persulfate, see abstract, p. 442, 447.

Claims 1-3, 11, 12, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Schwinn et al. '603, Schwinn et al. '794, or Schwinn et al. '187.

The references each teach antithrombin III incubated with ammonium sulfate. The pH is at 8.0, see example 1, in each patent.

Claims 1-3, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Eibl et al. '232

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The reference teaches antithrombin III incubated with ammonium sulfate, see examples 9 and 11.

Claims 1-3, 14-16, 17, are rejected under 35 U.S.C. 102(b) as being anticipated by Eibl et al. '084.

The reference teaches incubating antithrombin III in ammonium sulfate and using heat to inactivate any viruses. See col. 3 and the claims.

Claims 1-3, 8, 11, 14-16, 17, are rejected under 35 U.S.C. 102(b) as being anticipated by Schwinn et al. '344.

The reference teaches that antithrombin III is incubated in ammonium sulfate with TRIS at a concentration of 2mM and at pH 8.5. The reference also teaches that the preparation is virus inactivated by heating, see col. 4, also see col. 8, and example 5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miller-Andersson et al. taken with Cahalan et al. '172, Cahalan et al. '108, or JP 11209399, Good et al. and Schwinn et al. '344.

The reference teaches that antithrombin III is purified using affinity chromatography using ammonium persulfate, see abstract, p. 442, 447.

Good teaches that PIPES, TRIS, MES and HEPES are all known "Good's zwitterionic buffers" and that they are all known to be used as such.

The Cahalan references and JP teach that HEPES and MES buffers are known to be used to buffer antithrombin III.

Schwinn teaches that antithrombin III is incubated in ammonium sulfate with TRIS at a concentration of 2mM and at pH 8.5. The reference also teaches that the preparation is virus inactivated by heating, see col. 4, also see col. 8, and example 5.

Thus it would have been obvious to perform the claimed process since the buffers are well known to be used interchangeably and are well known to be commonly used as buffers. Further, virus inactivation with heat is well known to be done with antithrombin III as well as the pH range.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eibl et al. '232 taken with Cahalan et al. '172, Cahalan et al. '108, or JP 11209399, Miller-Andersson et al. (Miller), Good et al. and Schwinn et al. '344.

The teachings of Eibl are above.

The teachings of Miller are above.

Good teaches that PIPES, TRIS, MES and HEPES are all known "Good's zwitterionic buffers" and that they are all known to be used as such.

The Cahalan references and JP teach that HEPES and MES buffers are known to be used to buffer antithrombin III.

Schwinn teaches that antithrombin III is incubated in ammonium sulfate with TRIS at a concentration of 2mM and at pH 8.5. The reference also teaches that the preparation is virus inactivated by heating, see col. 4, also see col. 8, and example 5.

Thus it would have been obvious to perform the claimed process since the buffers are well known to be used interchangeably and are well known to be commonly used as buffers. Further, virus inactivation with heat is well known to be done with antithrombin III as well as the pH range and using affinity chromatography.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwinn et al. '603, Schwinn et al. '794, or Schwinn et al. '187 taken with Eibl et al. '084 or Schwinn et al. '344, Cahalan et al. '172, Cahalan et al. '108, or JP 11209399, Miller-Andersson et al. (Miller) and Good et al.

Schwinn et al. '603, Schwinn et al. '794, or Schwinn et al. '187 each teach antithrombin III incubated with ammonium sulfate. The pH is at 8.0, see example 1, in each patent.

The teachings of Eibl and Schwinn '344 are above.

The teachings of Miller are above.

Good teaches that PIPES, TRIS, MES and HEPES are all known "Good's zwitterionic buffers" and that they are all known to be used as such.

The Cahalan references and JP teach that HEPES and MES buffers are known to be used to buffer antithrombin III.

Schwinn teaches that antithrombin III is incubated in ammonium sulfate with TRIS at a concentration of 2mM and at pH 8.5. The reference also teaches that the preparation is virus inactivated by heating, see col. 4, also see col. 8, and example 5.

Eibl et al. '084 teaches incubating antithrombin III in ammonium sulfate and using heat to inactivate any viruses. See col. 3 and the claims.

Thus it would have been obvious to perform the claimed process since the buffers are well known to be used interchangeably and are well known to be commonly used as buffers. Further, virus inactivation with heat is well known to be done with antithrombin III as well as the pH range and using affinity chromatography.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eibl et al. '084 taken with Cahalan et al. '172, Cahalan et al. '108, or JP 11209399, Miller-Andersson et al. (Miller) and Good et al.

Eibl teaches incubating antithrombin III in ammonium sulfate and using heat to inactivate any viruses. See col. 3 and the claims.

The teachings of the references are above.

Thus it would have been obvious to perform the claimed process since the buffers are well known to be used interchangeably and are well known to be commonly

used as buffers. Further, affinity chromatography is well known to be done with antithrombin III.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwinn et al. '344 taken with Cahalan et al. '172, Cahalan et al. '108, or JP 11209399, Miller-Andersson et al. (Miller) and Good et al.

Schwinn teaches that antithrombin III is incubated in ammonium sulfate with TRIS at a concentration of 2mM and at pH 8.5. The reference also teaches that the preparation is virus inactivated by heating, see col. 4, also see col. 8, and example 5.

The teachings of the references are above.

Thus it would have been obvious to perform the claimed process since the buffers are well known to be used interchangeably and are well known to be commonly used as buffers. Further, affinity chromatography is well known to be done with antithrombin III.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 703-308-4230. The examiner can normally be reached on Monday thru Friday: 9:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone

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numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'M. Meller', with a stylized flourish at the end.

Michael V. Meller
Examiner
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MVM
November 19, 2002